BU

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 December 2001 (20.12.2001)

PCT

(10) International Publication Number
WO 01/95803 A1

(51) International Patent Classification[7]: A61B 5/113, 5/00

(21) International Application Number: PCT/US01/19056

(22) International Filing Date: 14 June 2001 (14.06.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
00112680.4 15 June 2000 (15.06.2000) EP

(71) Applicant *(for all designated States except US)*: **THE PROCTER & GAMBLE COMPANY** [US/US]; One Procter & Gamble Plaza, Cincinnati, OH 45202 (US).

(72) Inventors; and

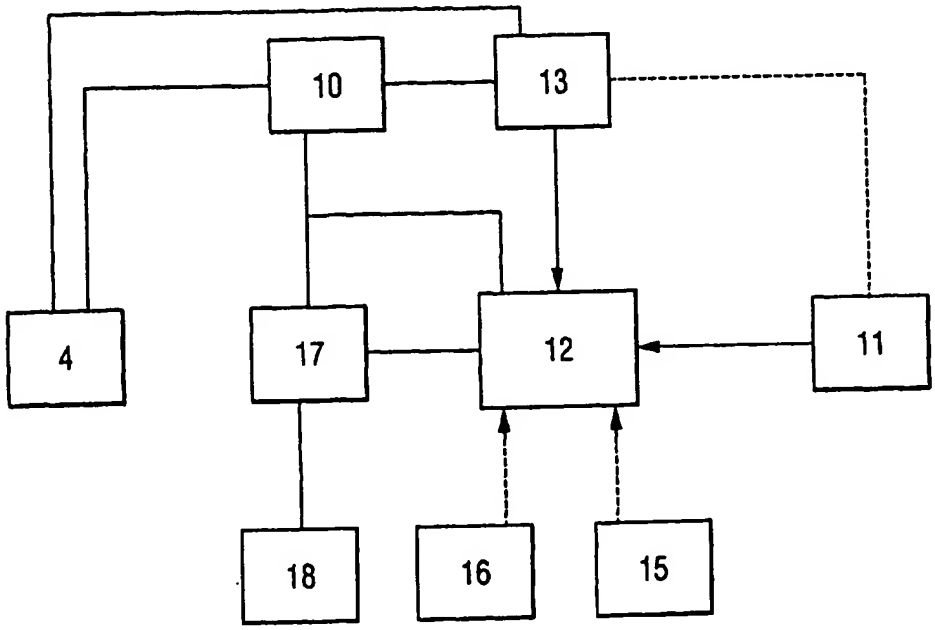
(75) Inventors/Applicants *(for US only)*: **BARRON, Bradford, S.** [US/BE]; Neerhoflaan 35, B-1780 Wemmel (BE). **BOSWELL, Emily, Charlotte** [GB/GB]; 45 Harvesters Close, Isleworth, Middlesex TW7 7PP (GB). **DAUGER-STRAUSS, Corine** [FR/BE]; Avenue du Commondant Lothaire, B-1040 Brussels (BE). **DEFLANDER, Joseph, Fernand** [BE/BE]; Elleveldweg 22, B-2990 Wespelaar (BE). **MACGILP, Neil, Archibald** [GB/GB]; Bankfield, Snowdenham Links Road, Surrey GU5 0BX (GB). **VAN DEN WOUWER, Chris** [BE/BE]; Bisschoppenhoflaan 400, B-2100 Deurne (BE). **EWART, Keith** [GB/GB]; 127 Harefield Road, Uxbridge UB8 1PN (GB).

(74) Common Representative: **REED, T., David**; c/o The Procter & Gamble Company, 5299 Spring Grove Avenue, Cincinnati, OH 45217 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,

[Continued on next page]

(54) Title: SYSTEM FOR BODY ACTIVITY DETECTION AND PROCESSING



(57) Abstract: A system for monitoring body activity having a device arranged for stand-alone attachment to a body in use. The device comprises: an actimetry sensor (11) for measuring body activity, and storage means (12) for receiving data from the actimetry sensor and storing it. Means analyses (17) the stored data to provide advisory information and a display (4) displays the advisory information to a user.

WO 01/95803 A1

MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) **Designated States** *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SYSTEM FOR BODY ACTIVITY DETECTION AND PROCESSING

This invention relates to the detection of body activity, such as sleep patterns, and the analysis of data related to such functions for provision to a user.

In recent years there has been much study of body functions, such as sleep activity, and associated analysis of the relevance of such functions to the general health of the body and the body's need for appropriate body functions (such as sleep patterns) to occur on a regular basis for adequate periods of time. As part of this research numerous devices have been proposed to assist in such measurement and analysis.

For example, WO-A-9714354 discloses a device and corresponding method which collects data for analysing sleep disturbances so that such data can be interpreted by a specialist at a future date.

However, this type of device requires operation by a highly skilled user and provides analysis which is difficult to interpret by anybody other than a specialist, as well as being expensive and sometimes unreliable. Furthermore, it is unable to provide a detailed history over an extended time period for an individual.

Other systems are uncomfortable, cannot be worn for extended periods and/or cannot be worn without restricting body movement.

According to the present invention there is provided a system for monitoring body activity comprising:

a monitoring device comprising: an actimetry sensor for measuring body activity; and data transmitting means for transmitting body activity data;

a device for providing data external to the body; and data transmitting mans for transmitting external data;

data receiving means separate from the monitoring device for receiving the transmitted data from the monitoring and device and from the device for providing external data;

means for analysing the received data to provide advisory information; and means for displaying the advisory information to a user.

The monitoring device may further comprise storage means for receiving data from the actimetry sensor and storing it.

The actimetry sensor may be an accelerometer such as a piezoelectric or MEMS accelerometer, or may be a simple motion sensor or a tilt switch, for example.

The body activity being monitored may be sleep.

The storage means may store data from the actimetry sensor together with temporal information. In such a case, the means for analysing the stored data provides processing based upon both body activity information and temporal information to provide advisory information to the user.

The advisory information provided to the user may include an indication of the quality of the activity, such as the quantity or quality of the sleep, whether or not the duration of the activity is sufficient, an indication as to whether the total amount of the activity over an extended period is acceptable, as well other data related to other long term body activity, for example.

The device can be configured to detect activity during the day. Daytime activity may be then analysed to indicate the most active and least active time during the day, so that information can be gathered in terms of the best time of day to attend a meeting, carry out exercise etc. The body activity that is measured can, as well as being actual time slept, be the number of awakenings, an indication as to how intermittent the sleep was, time taken before sleep, the number of and length of sleep interruptions, sleep proficiency, the number minutes immobile/moving, etc. A selection or all of this information can be provided to identify the least and most active times during the day.

The system may include an input on the device or analysing means for receiving input data from a user, such as desired time to go to sleep, the need to awake early for a particular event, as well as possible information relating to the age of the user, their sex, as well as optionally additional information such as what they perceive their energy level to be or how their sleep the night before.

There may be provided a further sensor or sensors in the system to measure body pulse rate variability, blood pressure or other body activities such as respiration, eyelid movement. In this case, sleep phases, such as REM, slow light sleep, slow deep sleep, or paradoxical sleep may be monitored.

The device may be configured in the style of a wrist watch, and may be arranged with a display to receive data from the analysing means to provide the advisory information as well as to provide additional information to a user, such as time and date information.

The device for providing data external to the body may be any suitable device known in the art such as a clock, a thermometer, a photo sensor, a calendar, a positioning system such as GPS, and the like.

The means for displaying the advisory information may be a liquid crystal display, plasma display, etc.

The data transmitting means may be an infra red or other form of wireless transmitter. Alternatively, it may be a wire data connection for insertion into a receiving terminal acting as the data receiving means. In this latter case the system would be arranged for a user to remove the monitoring device and place it in the data receiving means in order to activate the transmission of data to the receiving means and onto the analysing means.

The analysing means may be an appropriately configured PC or may be a dedicated processing device. The display means may be formed as part of the device, in which case the device also has second data receiving means for receiving data from the analysing means. Alternatively, the display may be formed as part of the analysing means and separate from the device.

The analysing means may have further means for connecting it to a terminal remote from the system, so that the analysing means may communicate with an external reference source, which may be a larger database of information or may be a specialised human reference. In this case, the connection to the remote source of information may be via an internet-type connection.

An additional sensor may be included for detecting data relating to the environment in which the body is placed.

The quality of the sleep may be defined by a parameter "sleep quality index" (SQI) and may be represented by the equation

$$SQI = C + \sum_{i=1}^{n} C_i P_i$$

In this equation n=12 and the twelve parameters, P_i, may be respectively time in bed, sleep and time, actual sleep, time, actual sleep (%), sleep efficiency, sleep latency, sleep bouts, wake bouts, mean activity score, mean score inactive, mean wake bout time, and wake movement RMS. The constant C may be 52.42 and the constants C_i associated with each of the parameters P_i respectively may be -1.887, 0.572, 2.084, -0.3536, 0.1408, -0.018, 0.188, 0-2469, -1.2126, -0.226, -0.0112 and 0.001238.

Alternatively, the quality of the sleep may be represented by a parameter which may be biased by user supplied estimates. The parameters used in the biasing process may be time in bed, sleep end time, mean activity score and/or mean score inactive.

The invention is described for use in monitoring sleep patterns however, it may also be of use in monitoring alternative body activities. For example monitoring daily activity levels to indicate whether the user is achieving sufficient activity in a fitness regime, whilst on a diet, during recuperation or, when bed rest is necessary the level of activity of a patient determines whether bed sores will be prevented. A further example may be to study the activity of children who suffer attention deficit syndrome. There are many other scenarios where the standard equipment could be used to monitor the activity of people or even pets.

If further sensors were introduced such as a heart rate sensor the device could be used to monitor the heart rate either during sleep (to determine the different phases of sleep) or during sports activities to monitor the heart rate without the need for any cumbersome chest band. The device could also be used to determine how stressed somebody was and potentially warn of impending heart problems.

Introduction of a global positioning system, in combination with the actimetry sensor, would allow the device to be used to track the whereabouts and activity of children, old people (particularly Alzheimer's patients) or perhaps criminals on probation. If the actimetry sensor were used in combination with a clock, the device could be used to help control jet lag by recommending the best sleeping habits to cope with a particular difference in time zone.

One example of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a schematic, perspective view of components of a system according to the present invention;

Figure 2 is a schematic diagram showing some of the functionality of a system according to the invention;

Figure 3 to 6 are diagrams showing two possible displays from the system;

Figure 7 is a schematic diagram of the internal components of the system of Figure 1; and

Referring to Figure 1, a system according to the present invention has, in this example, a monitoring device 1 configured as a wrist watch-style device, with a strap 2 and a component-containing housing 3. On the outer surface of the housing 3 is an optional display 4, which in this case is a liquid crystal display.

The system further comprises a receiving device 5, often referred to as a docking station which, in use, can receive the monitoring device 1 and connect with it to retrieve data from the device 1. The receiving device 5 may be, in turn, connected to an analysing device 6, which in this case is an appropriately configured PC, although it could be a dedicated piece of hardware. In this case the receiving device 5 and analysing device 6 are shown as separate components, although this may not necessarily be the case. The analysing device 6 has its own display 7, and may optionally have the ability to connect to a remote terminal (not shown) via an internet link or some other form of communication device.

Referring to Figure 4, the device 1 of Figure 1 has a number of internal components. The device 1 is powered by a battery 10 (or another power supply) which supplies power to the other components of the device 1. An actimetry sensor 11 detects motion in the device 1 and hence motion in the body to which the device 1 is attached in use. The data from the actimetry sensor 11 is passed to a memory 12. A clock 13 also provides temporal data to the memory 12 and to the actimetry sensor 11 if necessary, as well as optionally to the display 4. In addition to the actimetry sensor 11, the device 1 may further comprise additional sensors 15, 16, which may detect blood pressure, pulse rate variation etc. Data from these additional optional sensors 15, 16 may also be forwarded to the memory 12.

As described above, the monitoring device 1 has the ability to send data to the receiving means 5 via a transmitter 20, in this case through a fixed connection between the two when the user places the monitoring device 1 in the receiving device 5. As an alternative, the monitoring device 4 may transmit and/or receive data from the receiving means 5 via a wireless link such as an infra red link. In this latter case, data from the memory 12 can be requested from analysing means 6, either on a regulated intermittent, continuous, or on a user-requested basis.

A wide variety of different forms of analysis may be performed by the analysing means 6.

Examples of the types of analysis that may be performed will now be described with reference to Figures 2 to 6.

The actimetry sensor 11 may provide information in relation to sleep duration and the type of sleep to the analysing means 6. This information can be analysed by the analysing means 6 to provide information to the display 4, simply in terms of the total number of hours of sleep obtained, although it may provide additional information in relation to the quality of the sleep and the expected value of that sleep in terms of an "energy bank". By using data stored in the memory 12 or as the base unit in an additional memory (not shown) over a number of days, weeks or months, the analysing means 6 may also provide information indicative of accumulated sleep deficit or sleep excess. As mentioned above, the data can be provided to a user as and when requested, and is arranged to be provided in a very simple format so that it does not need complex interpretation.

The analysing means 6 may employ a scale, for example the Stanford sleep scale, in order to score the monitored, sleep and provide relevant information to the user and to some subject we input from the user. The scale defines different levels of sleepiness as follows;

1 - feeling active, vital, alert, wide awake.
2 - functioning at a high level, not at peak.
3 - relaxed, not full alertness, responsive.
4 - a little soggy, not at peak, let down.
5 - tired, losing interest, slowed down.
6 - drowsy, prefer to be lying down.
7 - almost in a reverie, hard to stay awake.

This scale can be shown to a user so that the user can input an indication of how tired they consider themselves to be. For example, the user could be prompted to input an indication as to how they feel when they wake up, with an indication as to the reasons for their feelings being provided by the analysing means 6 from the data collected.

In another example, such an input could be employed during the initial weeks of employing the device to help the system determine whether or not the user is sleeping for the right amount of time for them. For example, on the first day of wearing the device the system may prompt the user to indicate how much sleep they consider they need. It could then provide information regarding the average sleep requirement for someone of their age and sex. However, as the requirements vary from user to user, the system can then monitor sleep over a given period and prompt the user for feedback, not only at the time during the day in order to form a sleep diary in the memory of the system. The system may then be configured to adapt the indications that it gives the user, based upon the feedback and wake the user at the appropriate time, and then employing a sleep bank once the user's particular requirements have been determined.

The device 1 may have an alarm 18, which can be used simply to wake the user, in the manner of a normal wrist watch alarm, although it may be activated by the analysing means 6 (in conjunction with a heart rate monitor), when it is detected that an appropriate type of sleep is occurring to ensure gentle waking of the user.

If additional sensors 15, 16 are provided then additional analysis can be performed dependent upon the type of sensor to provide additional or more detailed and accurate information to the user. If the sensors detect parameters external to the body, such as light, location, sound, air temperature, humidity, barometric pressure, then this information may be compared with information relating to body

activity in order to adjust their information. If the sensors determine additional body activity, and detect one or more of muscle tonus, skin temperature, galvanic skin response, etc then additional analysis of the quality of the sleep may be provided.

As a further example, if a blood pressure sensor is employed then additional indications related to general levels of health and activity not specifically related to sleep alone can be provided by the analysing means. If a pulse rate variability detector is employed then this can assist in determining the type of sleep detected, and can provide further information in relation to whether an acceptable level of aerobic exercise has been performed within the allotted time period, whether it be a day, a week or a month.

If the system provides some form of "sleep bank" indication over a period of time (generally 7 days), then the sleep bank may calculate the information to be provided to the user by including a formula such as:

sleep bank (i) = sleep bank (i-1) + (sleep (i) - need) where "sleep bank" is the accumulated sleep balance on day i, "sleep" is sleep achieved on the night before day i and "need" is sleep needed (which can change dependent upon other measured parameters, or upon stored data, or can be set manually).

In the case when the analysing means 6 has a line to a remote station, more complex analysis can be performed and it may be possible for the analysing means 6 also to request and obtain data from a human specialist or an extended database so that additional information can be provided to the user.

In addition, the system enables the storage of long term data in such a manner that it can be tracked to give a high quality user history for treatment, as well as for identifying long term trends that would not come to light in a short term analysis.

In a further example the additional analysing means 6 may not be provided. In this case, the receiving device (or docking station) 5 may be configured to perform the analysis procedure, whilst the level of analysis would necessarily be less comprehensive than the analysing means 6, due to the reduced processing capacity, the unit still provides a useful function to the user. The docking station 5, illustrated in figure 5, is provided with a display 31 and two control knobs 33,34 to enable the user to select and display information from the analyses performed by the unit 5. Recess 32 is provided to locate the sensor device 1 in the correct relative position to assist in downloading the information stored within it.

In use, the sensor device 1 will be initialised in the docking station 5 prior to use (i.e. before bed time). When the user wishes to retire the sensor device 1 will be removed from the docking station 5 and placed on the wrist. The docking station 5 comprises its own internal clocking mechanism and hence removing the sensor device 1 from the recess 32 on the docking station 5 will automatically provide "bed time" information. Similarly "wake time" will automatically be recorded when the sensor device 1 is replaced into the recess 32 of the docking station 5 the following morning. This facility reduces the need for the user to keep a paper "sleep diary" and consequently makes the system easier to use.

Alternatively the monitoring device 1 may not comprise a storage facility 12. In this case the data acquired by the actimetry sensor would be transmitted directly to the docking station 5 for storage in real time.

Provision of a more sophisticated docking station 5, as seen in this example, removes the need for a user to have a computer available to perform the analyses. However the level of analysis achieved, as described above, may be less comprehensive. The docking station 5 is a highly portable unit that may easily be taken periodically, typically fortnightly, to an expert sleep analyst for further

interrogation and more detailed advice. A download facility is provided within the docking station 5 to further assist in this interrogation process.

The sleep expert will provide a more detailed analysis of the user's sleep patterns. For example, in order to provide a measure of sleep quality, as described above, a parameter "Sleep Quality Index" (SQI) may be provided. The algorithm for this parameter, SQI, is based upon many of the parameters which are easily monitored, or derived, by the invention. The algorithm is of the form

$$SQI = C + \sum_{i=1}^{n} C_i P_i$$

This algorithm uses twelve parameters and their associated constants (i.e. n=12). The parameters are

Time in bed*	Sleep efficiency	Mean wake bout time
Sleep end*	Sleep latency	Mean activity score*
Actual sleep time	Sleep bouts	Mean score inactive*
Actual sleep (%)	Wake bouts	Wake movement RMS

Corresponding constants may be defined by the values 52.42, -1.887, 0.572, 2.084, -0.3536, 0.1408, -0.018, 0.188, -0.2469, -1.2126, -0.226, -0.0112, 0.001238. Alternatively, this algorithm can be tailored to represent an individual user to achieve results of greater accuracy.

Solution of this algorithm can be intensive in terms of processing requirements. Where the processing capacity is not extensive, as in the example where the docking station 5 is not supplemented by the analysing device 6, a simpler formulation is implemented. In this case, a value for quality of sleep is

estimated by the user and this value is modified, based on four of the monitored/derived parameters (those marked *) above. This basic interpretation of sleep quality gives a lower predictive accuracy, nevertheless it provides a useful gauge, on a day to day basis, for the user of the system.

CLAIMS

1. A system for monitoring body activity comprising:
a monitoring device comprising: an actimetry sensor for measuring body activity; and data transmitting means for transmitting body activity data;

a device for providing data external to the body; and data transmitting mans for transmitting external data;

data receiving means separate from the monitoring device for receiving the transmitted data from the monitoring and device and from the device for providing external data;

means for analysing the received data to provide advisory information; and

means for displaying the advisory information to a user.

2. The system of claim 1, wherein the monitoring device further comprises storage means for receiving data from the actimetry sensor and storing it.

3. The system of claim 1 or 2, wherein the actimetry sensor is an accelerometer such as a piezoelectric or MEMS accelerometer.

4. The system of any preceding claim, wherein the body activity being monitored is sleep.

5. The system of any preceding claim, wherein the storage means stores data from the actimetry sensor together with temporal information.

6. The system of claim 5, wherein the means for analysing the stored data provides processing based upon both body activity information and temporal information.

7. The system of any preceding claim, wherein the advisory information provided to the user includes an indication of the quality of the activity, including at least one of the quality of the sleep, whether or not the duration of the activity is sufficient, an indication as to whether the totalled amount of the activity over an extended period is acceptable, or other data related to other long term body activity.

8. The system of any preceding claim, wherein the actimetry sensor also measures body pulse rate, and/or blood pressure.

9. The system of claim 8 wherein, sleep phases of REM, slow light sleep, slow deep sleep, or paradoxical sleep are monitored.

10. The system of any preceding claim, wherein the device may be configured in the style of a wrist watch.

11. The system of claim 10, wherein the device includes an alarm.

12. The system of any preceding claim, wherein the means for displaying the advisory information is a liquid crystal display.

13. The system of claim 10, 11 or 12 wherein the display is attached to the monitoring device.

14. The system according to any preceding claim, wherein the analysing means has a communication link with a remote source of data.

15. The system of claim 14, wherein the remote station enables the input of additional data from a human operator.

16. The system of any preceding claim, wherein the receiving means and the transmitting means form a wireless communication link.

17. A system according to any one of claims 1 to 15, wherein the data receiving means is part of a docking station for receiving the device.

18. A system according to any preceding claim, wherein the analysing means performs analysis on the basis of data from a source other than the body.

19. A system according to claim 18, wherein the source is a further sensor for detecting data relating to the environment in which the body is placed.

20. A system according to claim 7, wherein the quality of the sleep is defined by a parameter "sleep quality index" (SQI) represented by the equation

$$SQI = C + \sum_{i=1}^{n} C_i P_i$$

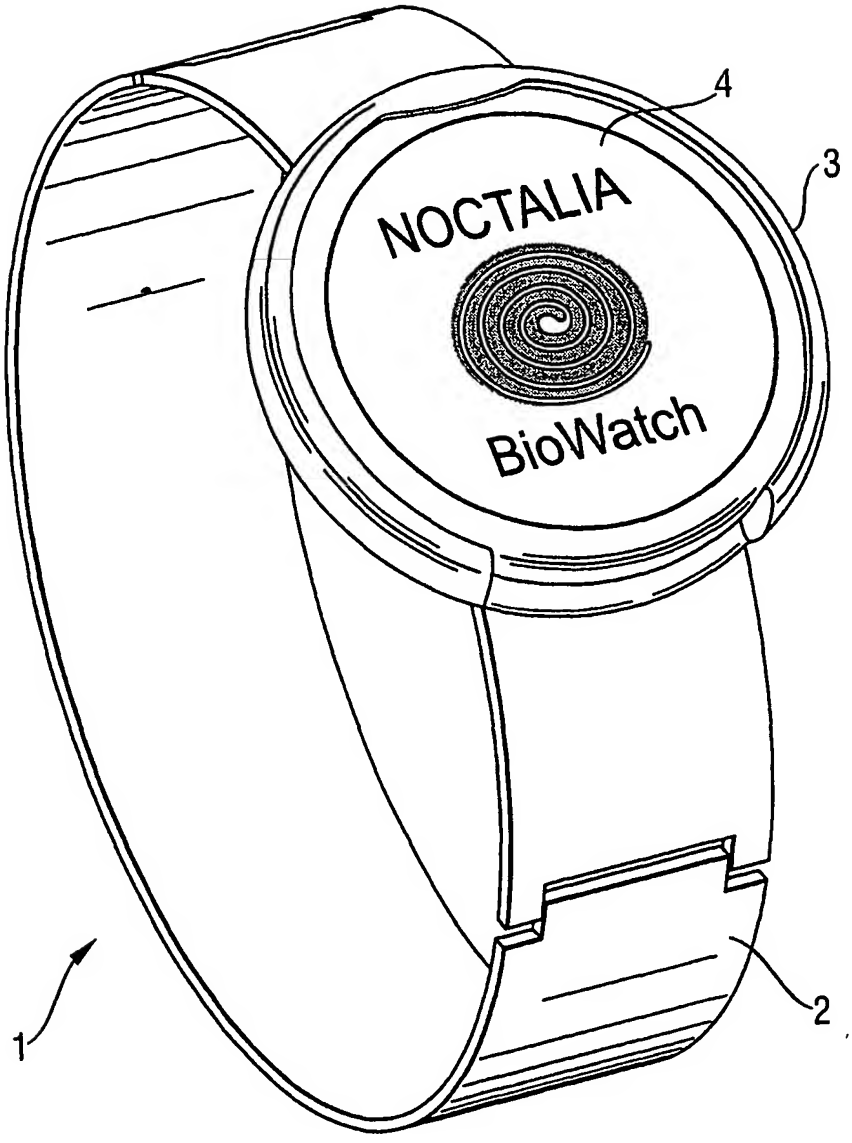
where n=12 and the twelve parameters, P_i, are respectively time in bed, sleep end time, actual sleep time, actual sleep (%), sleep efficiency, sleep latency, sleep bouts, wake bouts, mean activity score, mean score inactive, mean wake bout time, and wake movement RMS.

21. A system according to claim 20, wherein the constant C is 52.42 and the constants C_i associated with each of the parameters P_i respectively are -1.887, 0.572, 2.084, -0.3536, 0.1408, -0.018, 0.188, -0.2469, -1.2126, -0.226, -0.0112 and 0.001238.

22. A system according to claim 7, wherein the quality of the sleep is represented by a parameter biased user supplied estimate.

23. A system according to claim 22, wherein the parameters used in the biasing process are time in bed, sleep end time, mean activity score, mean score inactive.

24. A system according to any preceding claim, wherein the monitoring device is arranged for attachment to a body in use.


4
3
NOCTALIA
BioWatch
1
2

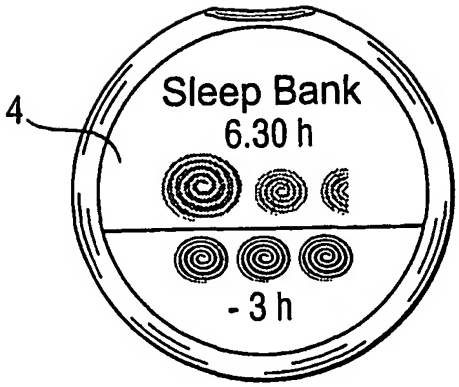


Fig. 2

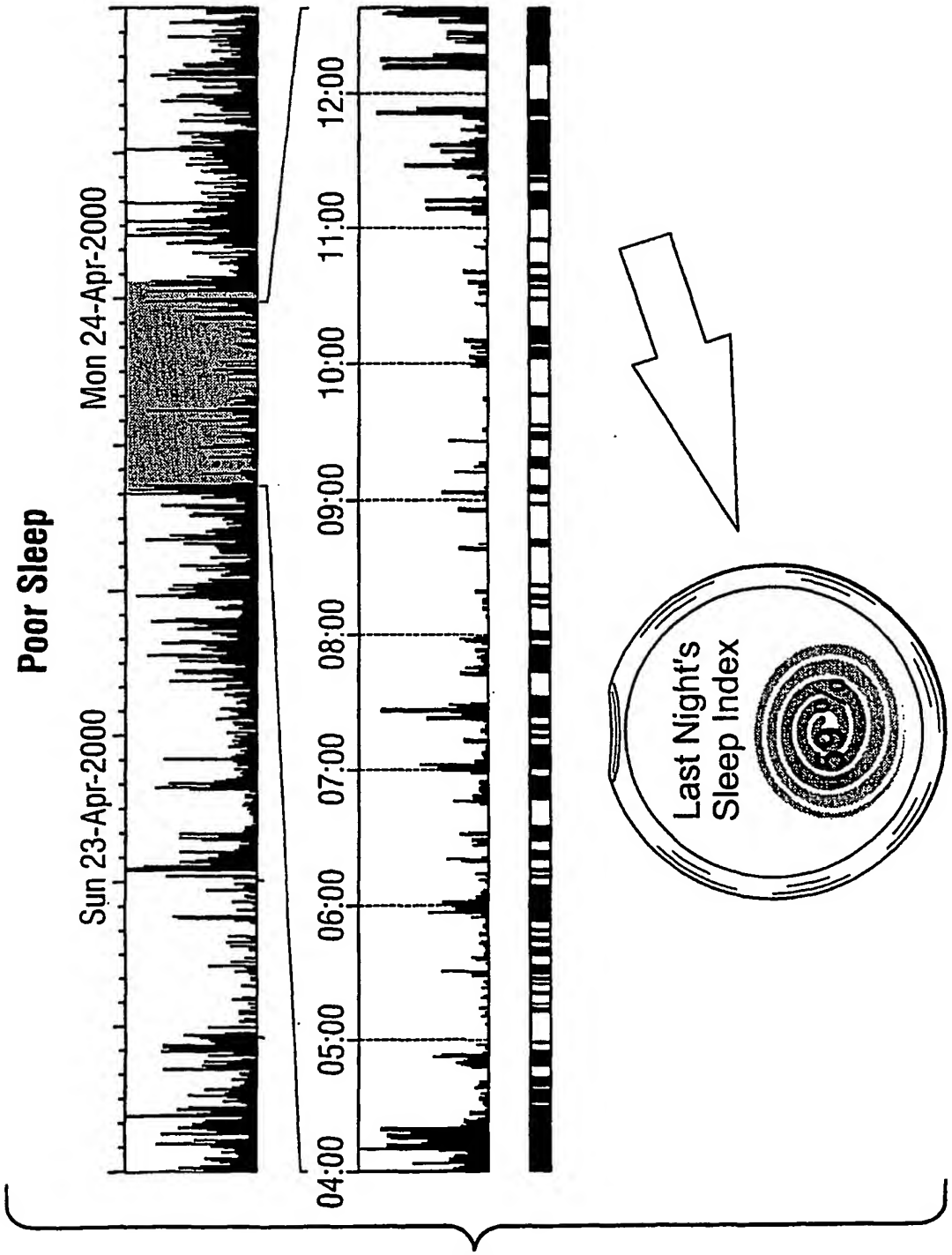

Poor Sleep
Sun 23-Apr-2000
Mon 24-Apr-2000
04:00
05:00
06:00
07:00
08:00
09:00
10:00
11:00
12:00
Last Night's
Sleep Index

Fig. 3

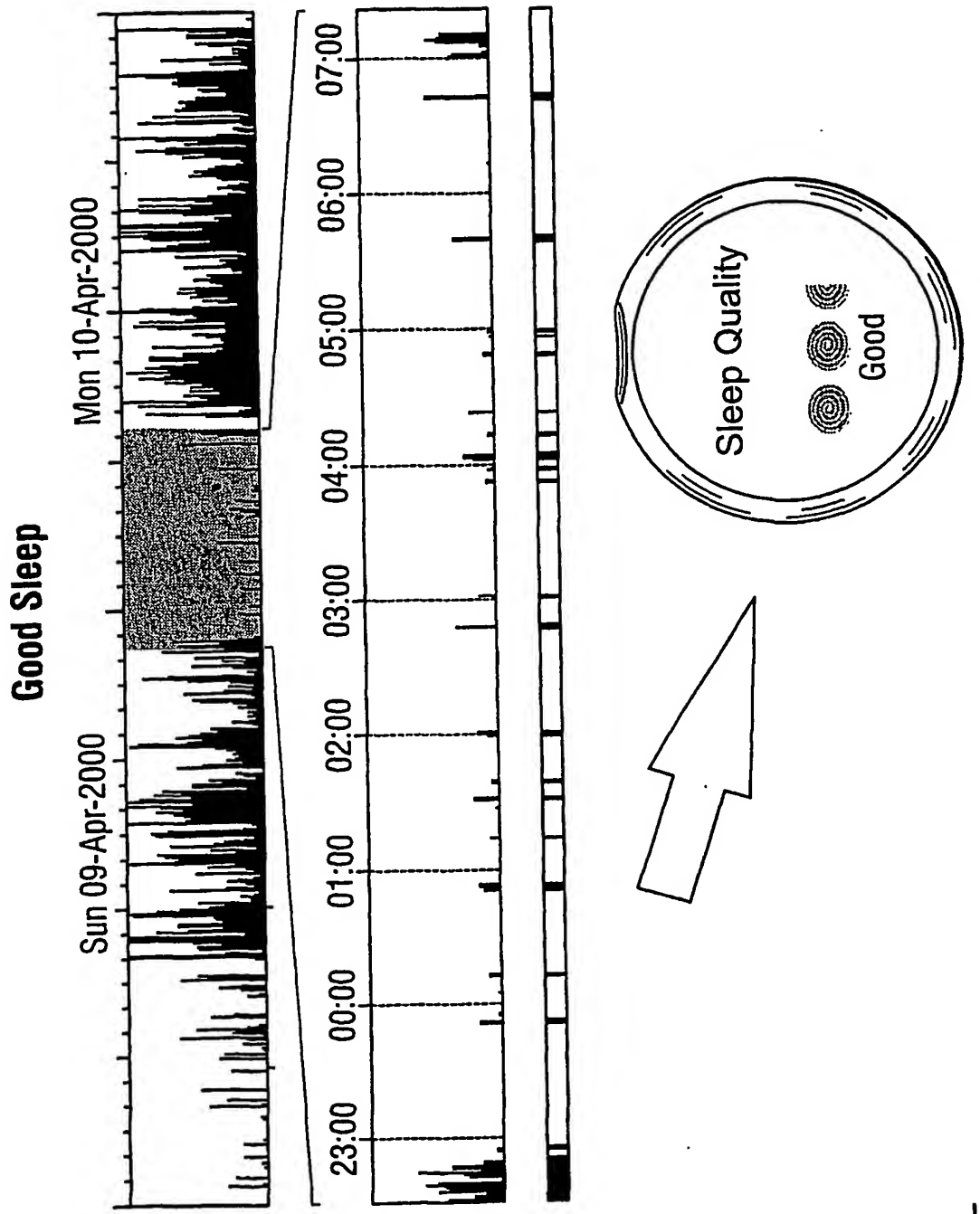

Good Sleep
Sun 09-Apr-2000
Mon 10-Apr-2000
23:00
00:00
01:00
02:00
03:00
04:00
05:00
06:00
07:00
Sleep Quality
Good

Fig. 4

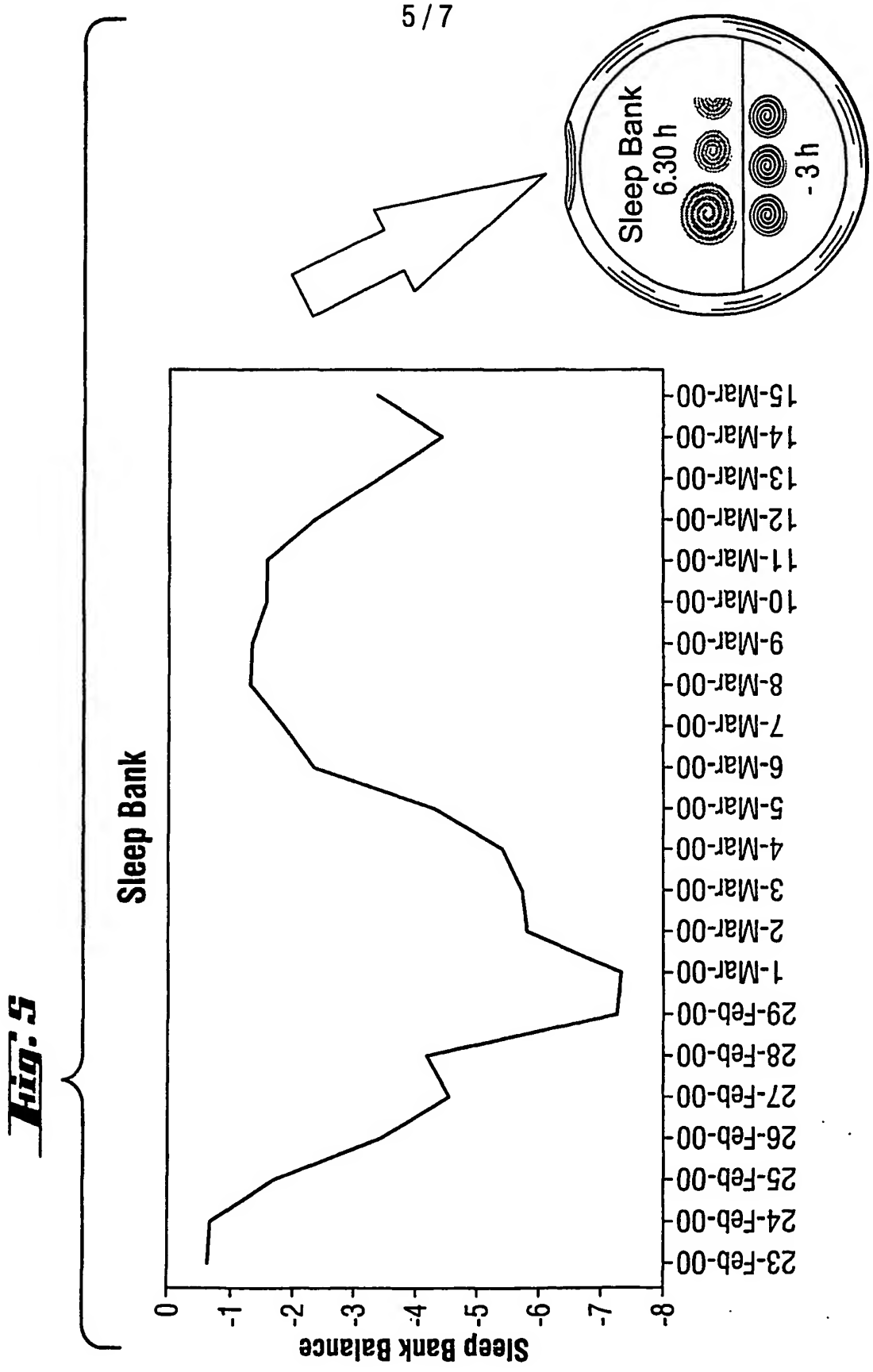

Sleep Bank
Sleep Bank Balance
0
-1
-2
-3
-4
-5
-6
-7
-8
23-Feb-00
24-Feb-00
25-Feb-00
26-Feb-00
27-Feb-00
28-Feb-00
29-Feb-00
1-Mar-00
2-Mar-00
3-Mar-00
4-Mar-00
5-Mar-00
6-Mar-00
7-Mar-00
8-Mar-00
9-Mar-00
10-Mar-00
11-Mar-00
12-Mar-00
13-Mar-00
14-Mar-00
15-Mar-00
Sleep Bank
6.30 h
- 3 h

Fig. 5

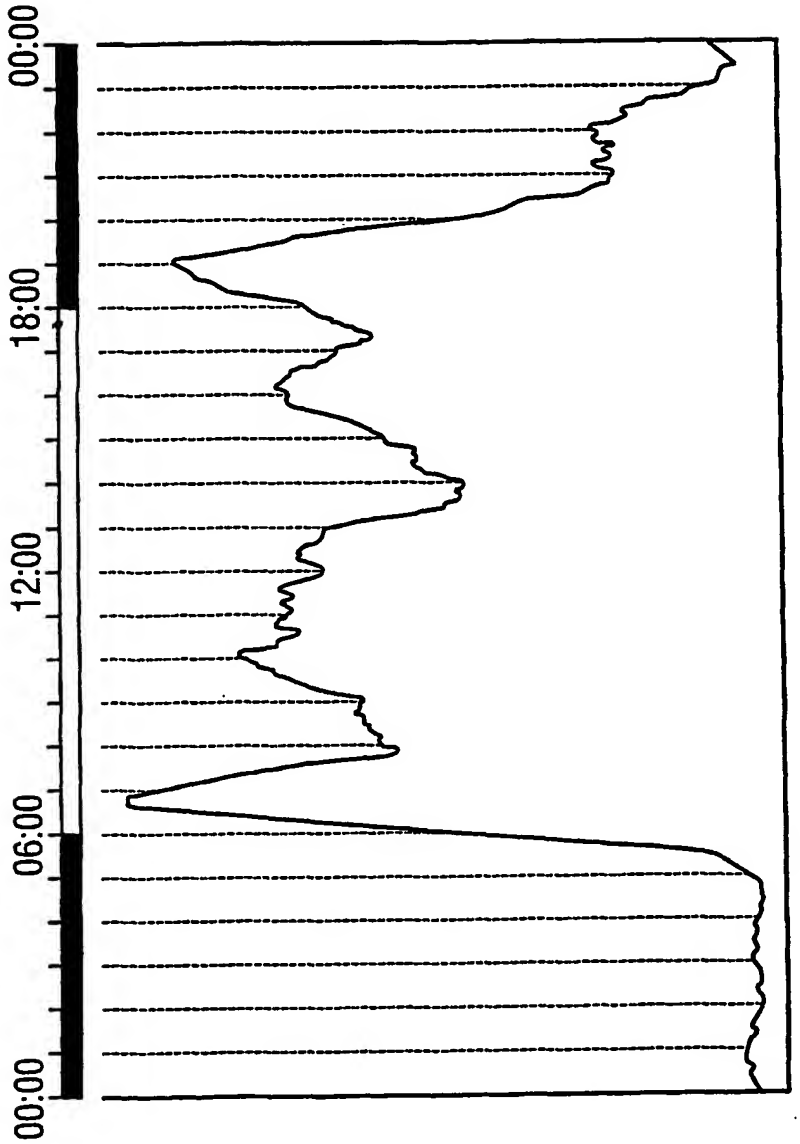
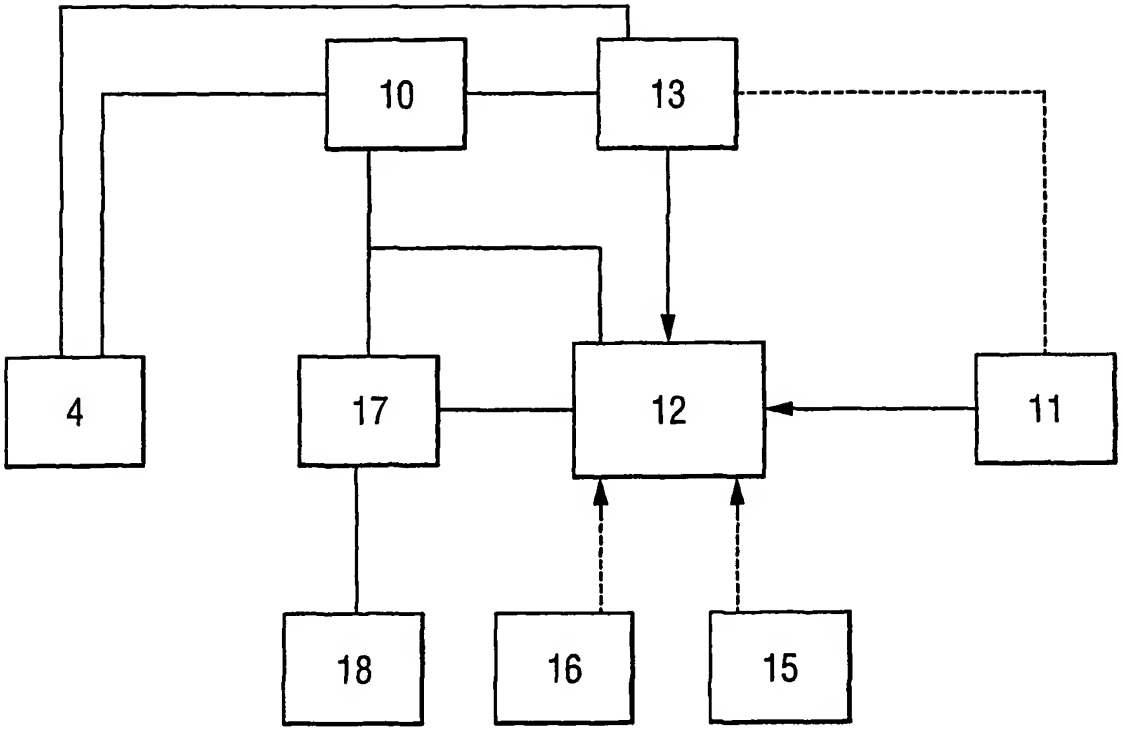


Fig. 6

Fig. 1



INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/US 01/19056

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/113 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ, INSPEC, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 2 679 453 A (UNIV RENNES) 29 January 1993 (1993-01-29)	1-12, 14-16, 18,19,24
A	page 7, line 10 -page 14, line 4; tables 1,2	20,22,23

Y	FR 2 727 850 A (ELA MEDICAL SA) 14 June 1996 (1996-06-14)	1-12, 14-16, 18,19,24
	page 10, line 1 - line 24 page 8, line 11 - line 18 page 6, line 14 - line 19; table 1	

A	EP 0 970 655 A (CARPE DIEM COMERCIAL SANITARIA) 12 January 2000 (2000-01-12) column 32, line 5 - line 29 column 31, line 35 - line 57	1,2, 12-16

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 August 2001	28/08/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Weihs, J

3

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 719 825 A (DOTTER JAMES E) 17 February 1998 (1998-02-17) column 1, line 28 - line 51	1,2,5,6, 8,10,16, 24
A	DE 196 42 316 A (KRISCHENOWSKI DIRK) 23 April 1998 (1998-04-23) column 3, line 6 - line 33	1,2,4,5, 22-24
A	BUYSSE D J ET AL: "THE PITTSBURGH SLEEP QUALITY INDEX A NEW INSTRUMENT FOR PSYCHIATRIC PRACTICE AND RESEARCH" PSYCHIATRY RESEARCH, vol. 28, no. 2, 1989, pages 193-214, XP001020700 ISSN: 0165-1781 abstract page 193	20

INTERNATIONAL SEARCH REPORT

information on patent family members

Inte nal Application No
PCT/US 01/19056

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2679453 A	29-01-1993	DE 69223969 D	12-02-1998
		EP 0597032 A	18-05-1994
		WO 9302731 A	18-02-1993
FR 2727850 A	14-06-1996	NONE	
EP 0970655 A	12-01-2000	ES 2124186 A	16-01-1999
		AU 5561698 A	07-08-1998
		BR 9807497 A	21-03-2000
		CN 1244104 T	09-02-2000
		WO 9831275 A	23-07-1998
US 5719825 A	17-02-1998	US 5848027 A	08-12-1998
DE 19642316 A	23-04-1998	NONE	